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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/480,472      06/06/95      MCDONOUGH      S      213/066

022249      HM12/0516  
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EXAMINER

MARSCHEL, A

ART UNIT

PAPER NUMBER

1631

30

DATE MAILED:

05/16/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

08/480,472

Applicant(s)

McDonough et al.

Examiner

Ardin Marsch I

Group Art Unit

1631



☒ Responsive to communication(s) filed on Feb 1, 2000 and Feb 28, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 39-42, 48-51, 54-56, 67-80, 82-93, and 95-169 is/are pending in the applicat

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☒ Claim(s) 100 is/are allowed.

☒ Claim(s) 39-42, 48-51, 54-56, 67-69, 71-76, 78-80, 84-86, 88-90, 92, 93, 95-99, 101-104, 106-122, 124-155, and 157-169 is/are rejected.

☒ Claim(s) 70, 77, 82, 83, 87, 91, 105, 123, and 156 is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Applicants' arguments, filed 2/1/00 and 2/28/00, have been fully considered and they are deemed to be persuasive regarding previous rejections of record. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Upon reconsideration, however, the following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application.

Claims 82, 83, 91, and 156 are objected to under 37 C.F.R. § 1.75(c) as being in improper form because a multiple dependent claim cannot properly depend from another multiply dependent claim. See M.P.E.P. § 608.01(n). Accordingly, claims 82, 83, 91, and 156 have not been further treated on the merits. Claims 83 and 156 contain this improper dependence via their dependence from claim 82.

Claims 50, 51, and 54 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 50 is vague and indefinite due to containing the phrase "The plurality of oligonucleotides of claim 40" in line 1 because this lacks antecedent basis because claim 40 does not

cite any such "plurality". Clarification is requested via clearer claim wording. This issue also applies to claims 51 and 54 due to their dependence.

PRIORITY of the Instant claims: It is noted that the earliest priority date for the instant claims directed to specific sequences which are hybridizable to reference sequences given in various instant claims is August 4, 1992. Consideration of the previous parents including 07/855,732 has failed to reveal enabling support for these instant claims. Therefore, the priority date given to the instant claims is August 4, 1992.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 39, 40, 67, 69, 71-76, 78-80, 84-86, 88-90, 95-99, 101-104, 106-122, 124-143, 147-151, 157-162, and 164-167 are rejected under 35 U.S.C. 102(e) as being anticipated by Kacian et al. (P/N 5,554,516).

It is noted that several of the instant sequences are identical to those disclosed in Kacian et al. (P/N 5,554,516) and

they are listed as follows:

	08/480,472	Kacian et al. (P/N 5,554,516)
SEQ ID NO:	1	14
	3	15
	4	16
	5	17
	6	10
	8	11
	9	12
	10	13

These identical sequences of Kacian et al. thus anticipate instant claims directed to such nucleic acids. The open claim language in instant claims 39 and 40 also results in an oligonucleotide comprising instant SEQ ID NO: 22 as being anticipated due to SEQ ID NO: 22 being contained within instant SEQ ID NO: 1 as a 3'-end subsegment. It is also observed that instant SEQ ID NO: 23 is a 3'-end subsegment of instant SEQ ID NO: 6. It is also noted that one embodiment of the kit of instant claim 39 is merely one oligonucleotide such as listed above and thus anticipated by disclosure of a single oligonucleotide. The instant plural oligonucleotide claims such as claim 89 are anticipated because several plural oligonucleotide examples are disclosed in Kacian et al. For example, EXAMPLE 10 starting at column 15 of Kacian et al.

includes SEQ ID NOs: 14 and 15 which correspond to instant SEQ ID NOs: 22 as a subsegment of NO: 1 and SEQ ID NO: 3. Other plural oligonucleotide examples of Kacian et al. result in anticipation of such plural oligonucleotide requiring instant claims. DMSO and glycerol as reaction components are cited in Kacian et al. in Example 9 starting at column 15 which anticipates instant claim 108 with the primer/probe contents that is disclosed in that Example. The molar ratio of instant claim 110 is anticipated in Example 10 in columns 15-16 of Kacian et al.

The above applied reference has several common inventors with the instant application, but not entirely the same inventorship. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim 98 is rejected under 35 U.S.C. § 102(e) as being clearly anticipated by Young(P/N 5,422,242).

Young discloses in its sequence listing SEQ ID NO: 5 which identically matches a 24 base subsegment of instant SEQ ID NO: 3. Thus, the Young nucleic acid hybridizes to the complement of

instant SEQ ID NO: 3 as required in instant claim 98. A helper probe is also required in instant claim 98 which is anticipated by claim 10 of Young wherein SEQ ID NO: 5 therein is combined with the nucleic acids of claim 8 due to its dependence in Young from claim 8.

Claims 74, 75, 147-149, and 152 are rejected under 35 U.S.C. § 102(e) as being clearly anticipated by Shah et al. (P/N 5,521,300).

Shah et al. discloses in its sequence listing SEQ ID NO: 48 which identically matches a 24 base subsegment of the complement of instant SEQ ID NO: 7. This nucleic acid anticipates the above listed instant claims due to its hybridization limitations.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 39-42, 48-51, 54-56, 67-69, 71-76, 78-80, 84-86, 88-90, 92, 93, 95-99, 101-104, 106-122, 124-155, and 157-169 are rejected under U.S.C. 103(a) as being unpatentable over Kacian et al. (P/N 5,554,516).

Kacian et al. (P/N 5,554,516) at column 4, lines 54-65, describes preferred embodiments wherein promoter-primers contain 3'-end modifications which inhibits or prohibits extension reactions in that direction. Since SEQ ID NO: 14 of Kacian et al. is clearly such a promoter-primer composition as noted in the above 102(e) rejection based on Kacian et al., the above noted column 4 citation is deemed to suggest and motivate additionally a 3' modification thereto as also instantly claimed in claim 50. This issue also applies to instant claims 39 and 40 due to the open claim language therein and as claim 50 depends from claim 40. It is additionally noted that instant SEQ ID NO: 3 is identical to SEQ ID NO: 15 of Kacian et al. It is also noted that kits as required in instant claim 39 is suggested in Kacian et al. at column 5, lines 57-62. The utilization of a mixture of



promoter-primers which includes both modified and unmodified 3'-ends is suggested in Kacian et al. at column 5, lines 25-30, which along with the specific sequences noted above regarding Kacian et al. suggests and motivates the practice of instant claim 51. The practice of different 3'-end modifications in a mixture is also suggested and motivated in Kacian et al. at column 9, lines 30-32, as also required in instant claim 54. Labeled oligonucleotides that are complementary or hybridize to target nucleic acids to the above noted sequences is suggested in Kacian et al. at column 14, lines 42-44 and 64-67, which suggests and motivates these sequences as being labeled, including with acridinium esters as required in instant claims 92 and 93. Example 12 in Kacian et al. at columns 16-17 exemplify RNA target practice which suggests and motivates instant claims 102 and 103. The Preface to the EXAMPLES in Kacian et al. in columns 11-12 indicates the presence or RNaseH or not in various polymerases that are utilized for primer extension which suggests and motivates RNaseH activity as also required in instant claim 104. Example 8 of the reference suggests and motivates additives as also required in instant claim 108.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the promoter-primer of instant SEQ ID NOs: 1 or 22 as noted in the above 102(e) rejection over Kacian et al. wherein a preferred

embodiment as given in Kacian et al. at column 4 is a 3'-end modification thus resulting in the practice of instant claim 50 as well as other instant claims as discussed above. Kits of claim 39 are also suggested as given above regarding column 5, lines 57-62, of Kacian et al.

The above applied reference has several common inventors with the instant application. Based on the earlier effective filing U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c).

Hammond (P/N 5,906,917) is cited on the enclosed PTO Form 892 as being of interest in disclosing certain of the nucleic acid sequences such as instant SEQ ID NOs: 8-10 or their

complements.

Claims 70, 77, 87, 105, and 123 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 100 is allowed.

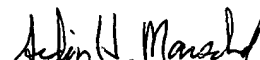
Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

May 15, 2000

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER